

REMARKS

The following remarks are submitted in response to the Office Action mailed February 11, 2004. Claims 1-52 and 137-219 were withdrawn from consideration. Therefore, claims 53-136 are pending and remain under consideration. No new matter has been added. Reconsideration, reexamination and allowance of the pending claims is respectfully requested.

AMENDMENTS TO THE SPECIFICATION

Clarifying amendments have been made to the specification primarily to correct typographical errors and reference numbering. No new matter has been added.

DRAWING OBJECTIONS

In paragraph 3 of the Office Action, the Examiner objects to Figure 23B. The examiner correctly notes that element number 228 is missing from the figure. Applicants respectfully submit an amended Figure 23B properly identifying missing element number 228.

CLAIM OBJECTIONS

In paragraph 4 of the Office Action, the Examiner objects to claims 64-69 and 106-111 because of various claim language informalities. Applicants have reviewed and amended the claims to correct the informalities noted by the Examiner.

SUBJECT-MATTER INDICATED AS ALLOWABLE

Applicants respectfully thank the Examiner for the indication that claim 76 would be allowable if rewritten in independent form including all of the limitations of the base claim and intervening claims. Claim 76 has been amended to be so rewritten and is, therefore, in condition for allowance. Withdrawal of the objection to claim 76 for being dependent on a rejected base claim is respectfully requested.

THE 35 U.S.C. § 112 CLAIM REJECTIONS

In paragraphs 5 and 6 of the Office Action, the Examiner rejects claims 74, and 90-136 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 74 and 116 have been amended, and now recite “the first electrode”. Withdrawal of this rejection is, therefore, respectfully requested.

With regard to claims 90-94, claim 90 has been amended to recite that the second electrode is spaced from the first electrode by a length such that when the first electrode is disposed at a first predetermined subcutaneous position between the third rib and the twelfth rib within the patient, the length of the spacing provides for the second electrode to be disposed at a second predetermined subcutaneous position between the third rib and the twelfth rib within the patient such that a depolarization vector is defined between the first electrode and the second electrode. The recited length of the spacing between the first and second electrode is a definite structural limitation.

Furthermore, claim 90 now recites that the defined depolarization vector defines an angle of separation between the first electrode and the second electrode with respect to a point within the patient’s heart, and wherein a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes. Applicants submit that the reference to a point within the patient’s heart is not indefinite. Such language would be understood by one of skill in the art to include any point within the patient’s heart – a definite area within the patient. Applicants respectfully point out that mere breadth of a claim is not to be equated with indefiniteness. See MPEP 2173.04.

As such, Applicants respectfully submit that the subject matter of claims 90-94 is clear to one of skill in the art, and meets the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is, therefore, respectfully requested.

Similarly, claim 95 recites a structural length of spacing between the first and second subcutaneous electrodes, and recites a degree of separation between the first and second subcutaneous electrodes defined about the patient’s ribcage with respect to a point within the patient’s heart. As discussed above, such language would be understood by one of skill in the art to include any point within the patient’s heart – a definite area within the patient. As such,

Applicants respectfully submit that the subject matter of claim 95, and dependent claims 96-136, is clear to one of skill in the art, and meets the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is, therefore, respectfully requested.

THE 35 U.S.C. § 102 CLAIM REJECTIONS

In paragraphs 7 and 8 of the Office Action, the Examiner rejects claims 53-54, 59-61, 63, 72, 75, 84-90, 95-96, 101-103, 105, 114, 117-119, and 126-136 under 35 U.S.C. §102(b) as being anticipated by Adams (U.S. Patent No. 5,601,607). Applicants respectfully traverse this rejection, to the extent that it is maintained.

Applicants have amended independent claim 53 to recite, among other elements, that the first and second electrodes are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

Adams does not teach or suggest two subcutaneous electrodes where a cardioversion-defibrillation energy is delivered between the two subcutaneous electrodes. In Adams, a defibrillating system is disclosed including a pulse generator that may include an active housing (i.e., "active can"), and a subcutaneous patch electrode, but Adams does not teach or suggest delivering a cardioversion-defibrillation energy between two subcutaneous electrodes. In Adams, transvenous electrodes, such as an electrode positioned in the right-atrium (RA), the superior vena cava (SVC), or the right ventricular-apex (RVA) are used in conjunction with the active can or the subcutaneous patch electrode to deliver energy. There is no teaching or suggestion of delivering energy between the active can and the subcutaneous patch electrode. In fact, while describing one embodiment, Adams actually teaches away from delivering energy between a subcutaneous-patch electrode and an active can, as follows:

When a subcutaneous-patch or SUB electrode is present in addition to the RVA, SVC, and CAN electrodes, the list of patterns must be reconsidered. . . . Further a pattern with CAN and SUB having opposite polarities is rejected because the current from one to the other would be remote from the heart and wasted. (Adams, column 6, lines 29-35.)

Therefore, Adams does not teach the invention of claim 53. As such, it is believed that independent claim 53, and the claims depending there from, are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

Independent claim 95 was also amended, and now also recites, among other elements, that the first and second electrodes are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

As indicated above with regard to claim 53, Adams does not teach or suggest two subcutaneous electrodes where a cardioversion-defibrillation energy is delivered between the two subcutaneous electrodes. Therefore, Adams does not teach the invention of claim 95. As such, it is believed that independent claim 95, and the claims depending there from, are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

In paragraph 9 of the Office Action, the Examiner rejects claims 53-54, 63, 70-72, 74-75, 77, 84-90, 95-96, 105, 112-114, 117-119, and 126-136 under 35 U.S.C. §102(b) as being anticipated by Hauser et al. (U.S. Patent No. 5,385,574). Applicants respectfully traverse this rejection, to the extent that it is maintained.

As indicated above, independent claim 53 recites, among other elements, that the first and second electrodes are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

Hauser et al. do not teach or suggest this. Hauser et al. disclose an implantable intravenous cardiac stimulation system with a pulse generator housing serving as an additional electrode. Hauser et al. do indicate that a subcutaneous electrode may be used in the system, for example, at column 6, lines 8-17, but Hauser et al. do not teach or suggest delivering a cardioversion-defibrillation energy between two subcutaneous electrodes. In Hauser et al., transvenous electrodes, such as an electrode positioned in the right-atrium (RA), the superior vena cava (SVC), or the right ventricle (RV) are used in conjunction with the active can or the subcutaneous electrode to deliver energy. See, Hauser et al. column 4, line 56 through column 5, line 2; and column 5, line 67 through column 6, line 17. There is no teaching or suggestion of delivering energy between the active can and the subcutaneous electrode. As such, there is no teaching or suggestion of first and second subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

Therefore, Hauser et al. do not teach the invention of claim 53. As such, it is believed that independent claim 53, and the claims depending there from, are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

As discussed above, also recites, among other elements, that the first and second electrodes are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

As indicated above with regard to claim 53, Hauser et al. do not teach or suggest two subcutaneous electrodes where a cardioversion-defibrillation energy is delivered between the two subcutaneous electrodes. Therefore, Hauser et al. do not teach the invention of claim 95. As such, it is believed that independent claim 95, and the claims depending there from, are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

The 35 U.S.C. § 103 Claim Rejections

In paragraphs 10-12 of the Office Action, the Examiner rejects claims 55-58, 73, 78-83, 91-94, 97-100, 115, and 120-125 under 35 U.S.C. §103(a) as being unpatentable over Adams and also unpatentable over Hauser et al.. Applicants respectfully traverse this rejection, to the extent that it is maintained.

As discussed above, amended independent claims 53 and 95 each recite that the first and second electrodes are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes. Also as discussed above, neither Adams, nor Hauser et al. teach or suggest two subcutaneous electrodes where a cardioversion-defibrillation energy is delivered between the two subcutaneous electrodes. Therefore, it is believed that independent claims 53 and 95, and the claims depending from either (including claims 55-58, 73, 78-83, 91-94, 97-100, 115, and 120-125), are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

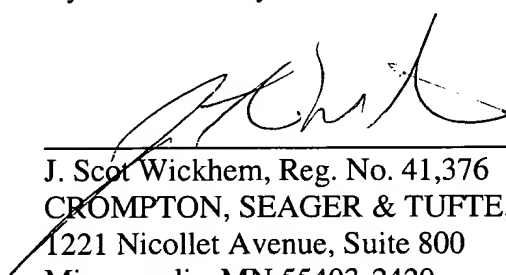
In paragraphs 13-18 of the Office Action, the Examiner rejects claims 59-62, 64-69, 70-71, 74, 101-104, 106-111, 112-113, and 116 under 35 U.S.C. §103(a) as being unpatentable over Adams and/or Hauser et al. in combination with each other and/or in combination with various references. Applicants respectfully traverse these rejections, to the extent that it they are maintained.

For the reasons stated above, both Adams and Hauser et al. fail to teach the basic elements of the independent claims 53 and 95. None of the cited references provide what Adams and Hauser et al. lack. In particular, none of the cited references teach or suggest first and second electrodes that are both subcutaneous electrodes, and that a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes. Thus, none of the combinations of references can be seen to render the claims obvious.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
Gust H. Bardy et al.
By their Attorney,

Date: May 11, 2004



J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

Attachment: One Replacement Drawing Sheet